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urt A. Summe, Reg. No. 36,023

Date /

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT PEDI-15A1/119

Applicants

: Gilbert R. Gonzales, et al.

Art Unit: 3763

Serial No.

: 10/817,224

Examiner: Not yet assigned

Filed

: April 2, 2002

For

: AUTOMATIC INJECTION DEVICE

Cincinnati, Ohio 45202

June 23, 2005

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of candor and good faith imposed by 37 CFR §1.56 and means of complying therewith according to 37 CFR §§1.97 and 1.98, the references listed on the attached forms PTO-1449 are called to the attention of the U.S. Patent and Trademark Office in connection with the above-identified application.

Subject to the Office's waiver of providing copies of U.S. patents and published applications for applications filed after June 30, 2003, only copies of the foreign patent references are provided, since this application was filed on April 2, 2004, and therefore, subsequent to June 30, 2003. Further subject to the Office's waiver, no copies of the U.S. patent applications listed in the "Other" category on Form PTO-1449 are provided.

DE19822031 is the priority document for U.S. Patent No. 6,280,421.

DE3241911 discloses an injector device.

DE3638984 discloses an injector device.

DE3900926 discloses an injector device.

DE4223958 discloses an injector device.

EP0245312 discloses an injector device.

EP0268191 discloses an injector device.

EP0373321 discloses an injector device.

EP0627229 discloses a dosing means for a syringe.

EP0956873 discloses a syringe and is a European counterpart claiming the same priority as U.S. Patent No. 6,280,421.

FR2650187 discloses a syringe.

FR2701211 discloses a syringe.

JP11347121 discloses a syringe and claims the same priority as U.S. Patent No. 6,280,421.

WO87/06895 discloses an injection instrument.

WO92/18179 discloses an injection device.

WO93/16740 discloses an injection device.

WO95/01812 discloses a needle system fastening mechanism.

The Examiner is respectfully requested to review each reference cited and to note the review on the attached PTO-1449 forms and to reach their own independent determination of its materiality, if any.

To the best of Applicants' knowledge and belief, this Information Disclosure

Statement is being filed prior to the receipt of a first Office Action on the Merits of this case, and therefore, no fees are believed to be due. However, if any charges or credits are necessary to complete this communication, please apply them to Deposit Account 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

Kurt A. Summe

Reg. No. 36,023

2700 Carew Tower Cincinnati, OH 45202 (513) 241-2324 (513) 421-7269 (facsimile)

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SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE 10/817,224 PEDI/15A1 (MODIFIED) **APPLICANT** INFORMATION DISCLOSURE STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **FILING DATE GROUP** (Use several sheets if necessary) (37 CFR 1.98(b)) April 1, 2004 U.S. PATENT DOCUMENTS FILING DATE **EXAMINER** ISSUE IF APPROPRIATE PATENT NUMBER **CLASS SUBCLASS** INITIAL DATE **PATENTEE** 4 2/9/88 B.A 2 3 9 Spencer 7 5/31/88 B.B 7 4 4 1 3 **Bloch** 8 5/31/88 Wolff et al. B.C 7 4 7 3 8 7 9 11/29/88 B.D 8 8 Levin et al. 6 2 12/6/88 B.E 4 7 8 9 6 Thomas-Leuquin et al. 0 4 3 7 2/14/89 B.F 4 8 Vaillancourt 3/21/89 B.G 4 8 1 3 4 2 6 Haber et al. 7/25/89 B.H 8 5 0 9 9 Zerbst et al. **B.I** 9 0 0 3 2/13/90 Stern et al. 1 4 9 2 4 9 5/1/90 Spier et al. B.J 1 0 B.K 9 3 5 0 1 6 6/19/90 Deleo FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS **PUBLICATION** TRANSLATION DOCUMENT COUNTRY OR **SUBCLASS CLASS** (YES/NO) NUMBER DATE **PATENT OFFICE EPO** EP058536 04/16/86 B.L EP245312 05/02/90 **EPO** Claims only B.M B.N EP268191 09/19/90 **EPO** Claims only EP298067 10/23/91 **EPO** B.O B.P EP327910 04/15/92 **EPO** B.Q EP373321 06/08/94 **EPO** Claims only OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) B.R Alchas et al., Prefillable Intradermal Injector, Pub. No. US 2001/0056263, 12/27/O1 Asbaghi, Protective Device for a Fillable Injection Syringe, Pub. No. US 2002/O004652, 1/10/O2 B.S Jansen et al., Safety Shield System for Prefilled Syringes, Pub. No. US 2002/O004649, 1/10/O2 B.T DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

Include a copy of this form with next communication to applicant.

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SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO. 10/817,224 (MODIFIED) PATENT AND TRADEMARK OFFICE PEDI/15A1 INFORMATION DISCLOSURE **APPLICANT** STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **GROUP** (Use several sheets if necessary) **FILING DATE** (37 CFR 1.98(b)) April 1, 2004 U.S. PATENT DOCUMENTS FILING DATE EXAMINER ISSUE IF APPROPRIATE **CLASS SUBCLASS** PATENT NUMBER DATE PATENTEE INITIAL 9 5/28/91 C.A 5 0 0 5 Hake 4/14/92 C.B 5 0 4 3 8 0 Holman et al. 1 2 3 0 5/12/92 Haber et al. C.C 5 1 1 7 5 08/11/92 5 3 Rand et al. C.D 1 6 8/25/92 5 0 C.E 5 4 1 0 Hake 8/25/92 C.F 5 4 4 9 Dalto et al. 1 1/5/93 C.G 5 7 6 6 4 3 Kramer et al. 1 C.H 5 7 8 6 0 9 1/12/93 Ishikawa 1 C.I 5 2 2 6 8 9 7/13/93 Haber et al. C.J 5 2 4 2 4 1 9/7/93 Hutson 6 C.K 5 2 4 6 4 2 8 9/21/93 Falknor FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS TRANSLATION DOCUMENT **PUBLICATION** COUNTRY OR SUBCLASS CLASS (YES/NO) NUMBER DATE PATENT OFFICE 07/19/95 **EPO** C.L EP498737 EP496141 04/02/97 **EPO** C.M 02/14/96 **EPO** C.N EP516473 2/3/93 **EPO** C.O EP525525 C.P EP554995 12/17/97 **EPO** C.Q EP573947 12/15/93 **EPO** OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) C.R Larsen et al., Disposable Double Pointed Injection Needle, and an Insulin Injection System Comprosing a Disposable Double Pointed Injection Needle, Pub. No. US 2002/0004648, 1/10/02 C.S Nelson et al., Single Use Disposable Jet Injector, Pub. No. US 2002/O007149, 1/17/O2 Hjertman et al., Medical Arrangement, Pub. No. US 2002/O007142, 1/17/O2 C.T DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO. 10/817,224 (MODIFIED) PATENT AND TRADEMARK OFFICE PEDI/15A1 **APPLICANT** INFORMATION DISCLOSURE STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **GROUP** (Use several sheets if necessary) FILING DATE (37 CFR 1.98(b)) April 1, 2004 **U.S. PATENT DOCUMENTS** FILING DATE **EXAMINER** ISSUE IF APPROPRIATE PATENT NUMBER **CLASS SUBCLASS** INITIAL DATE **PATENTEE** 0 0 2 10/5/93 Ehrlich et al. D.A 2 5 0 10/5/93 D.B 5 2 5 0 3 7 Bitdinger 12/28/93 D.C 5 2 7 3 5 4 Bell et al. 3 5 2 9 0 2 5 5 3/1/94 D.D Vallelunga et al. 3/22/94 5 2 9 5 9 D.E 6 3 Deeks D.F 5 3 0 0 0 3 0 4/5/94 Crossman et al. 4/19/94 D.G 5 3 0 4 1 4 9 Morigi 7/12/94 D.H 5 3 2 8 4 8 Sircom et al. 10/30/94 D.I 5 3 4 2 3 0 9 Hausser D.J 5 3 4 4 4 0 9/6/94 Benson D.K 5 3 4 8 5 4 9/20/94 Sweeney et al. FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS **DOCUMENT PUBLICATION COUNTRY OR TRANSLATION SUBCLASS** (YES/NO) **CLASS** NUMBER DATE **PATENT OFFICE** EP594349 07/15/98 **EPO** D.L D.M EP627229 04/21/99 **EPO** Claims only D.N EP956873 05/07/99 **EPO** FR2650187 D.O 2/1991 France D.P FR2701211 08/12/94 France No D.Q GB2202747 10/5/88 **United Kingdom** OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) D.R Buttgen et al., Cannula for Medical Syringes, Pub. No. US 2002/O010421, 1/24/O2 Sadowski et al., Needle Assisted Jet Injector, Pub. No. US 2002/O010456, 1/24/O2 D.S D.T Hill et al., Wet/Dry Automatic Injector Assembly, Pub. No. US 2002/O016563, 2/7/O2 **EXAMINER** DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE 10/817,224 (MODIFIED) PEDI/15A1 **APPLICANT** INFORMATION DISCLOSURE STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **GROUP** (Use several sheets if necessary) **FILING DATE** (37 CFR 1.98(b)) April 1, 2004 U.S. PATENT DOCUMENTS ISSUE FILING DATE EXAMINER IF APPROPRIATE PATENT NUMBER **CLASS SUBCLASS** INITIAL DATE **PATENTEE** 5 8 10/18/94 Hurley et al. E.A 3 5 6 0 7 12/27/94 E.B 5 3 7 3 Graves et al. 1/10/95 E.C 5 3 7 9 9 0 0 Gregg et al. 5 8 5 5 5 5 1/31/95 Hausser E.D 3 4/18/95 7 6 Simone et al. 5 4 0 6 E.E 1 E.F 9 4 6 4/25/95 Steinman 5 4 0 6/13/95 E.G 5 4 2 3 7 6 6 Di Cesare 2 6/13/95 E.H 5 4 3 6 6 Di Cesare 7/4/95 E.I 5 4 2 9 6 3 D'Amico E.J 5 4 2 9 6 7/4/95 Rait 1 E.K 5 4 3 7 6 4 8 8/1/95 Graves et al. FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS DOCUMENT **PUBLICATION** COUNTRY OR **TRANSLATION CLASS SUBCLASS** (YES/NO) PATENT OFFICE NUMBER DATE Abstract only JP11-347-121 12/21/99 Japan E.L E.M WO87/O2895 5/21/87 PCT Abstract only E.N WO91/10460 7/25/91 **PCT PCT** E.O WO92/18179 10/29/92 E.P WO93/16740 9/2/93 **PCT** E.Q WO93/O5835 1/4/93 **PCT** OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) E.R Hjertman, Medical Device, Pub. No. US 2002/O035348, 3/21/O2 Sadowski et al., Needle Assisted Jet Injector, Pub. No. US 2002/O045866, 4/18/O2 E.S Sadowski et al., Needle Assisted Jet Injector, Pub. No. US 2002/0072709, 6/13/02 E.T DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

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U.S. DEPARTMENT OF COMMERCE SUBSTITUTE FORM PTO-1449 ATTY. DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE PEDI/15A1 10/817.224 (MODIFIED) **APPLICANT** INFORMATION DISCLOSURE Gilbert R. Gonzales et al. STATEMENT BY APPLICANT **GROUP** (Use several sheets if necessary) **FILING DATE** April 1, 2004 (37 CFR 1.98(b)) **U.S. PATENT DOCUMENTS** FILING DATE **ISSUE EXAMINER** IF APPROPRIATE **CLASS SUBCLASS** PATENT NUMBER DATE **PATENTEE** INITIAL 5 3 2/4/97 Gyure et al. G.A 9 9 5 2/4/97 Marshall et al. G.B 5 9 9 3 0 9 6 0 5/13/97 Horstmann et al. G.C 5 2 9 0 3 G.D 5 6 2 9 2 9 9 05/13/97 Brown et al. 5 3 2 3 9 5/27/97 G.E 6 6 Burns 9 6/3/97 G.F 5 6 3 4 0 6 Haber et al. 7/1/97 2 2 5 6 4 3 Cosme G.G 0 7/1/97 2 Marshall et al. G.H 5 6 4 3 1 8/19/97 G.I 5 6 5 8 2 5 Reichenbach et al. 5 5 G.J 5 6 8 2 9 08/19/97 Pearson et al. G.K 5 6 6 2 9 2 1 9/2/97 Fein et al. FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS TRANSLATION DOCUMENT **PUBLICATION COUNTRY OR SUBCLASS** (YES/NO) PATENT OFFICE CLASS NUMBER DATE G.L G.M G.N G.O G.P G.Q OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) Enggaard, Automatic Injection Device with Reset Feature, Pub. No. US 2002/O120235, 8/29/O2 G.R Giambattista et al., Pen Needle and Safety Shield System, Pub. No. 2002/O133122, 9/19/O2 G.S Halseth et al., Catheter Insertion Device with Retractable Needle, Pub. No. US 2002/O161386, 10/31/O2 G.T **EXAMINER** DATE CONSIDERED

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U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. SUBSTITUTE FORM PTO-1449 PATENT AND TRADEMARK OFFICE PEDI/15A1 10/817,224 (MODIFIED) INFORMATION DISCLOSURE **APPLICANT** STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **GROUP** (Use several sheets if necessary) **FILING DATE** (37 CFR 1.98(b)) April 1, 2004 **U.S. PATENT DOCUMENTS** ISSUE FILING DATE **EXAMINER** IF APPROPRIATE INITIAL PATENT NUMBER **CLASS SUBCLASS** DATE **PATENTEE** 10/21/97 H.A 5 6 9 1 Hiertman et al. 2 11/18/97 H.B 5 6 8 8 4 1 Asbaghi 12/2/97 5 6 9 3 3 4 Schroeder et al. H.C H.D 5 6 9 5 4 7 12/9/97 Daugherty 8 2/3/98 5 3 6 6 Wilmot H.E 7 1 2 H.F 5 7 1 8 3 9 2/17/98 Newby et al. 9 2 2/17/98 H.G 5 7 1 1 2 Chiodini et al. 6 3 5/5/98 H.H 5 7 4 3 Capaccio et al. 5/5/98 H.I 5 7 4 6 2 5 Manjarrez H.J 5 7 4 6 2 5/5/98 Graves et al. H.K 5 7 7 9 6 7 7/14/98 Frezza FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS **DOCUMENT PUBLICATION** COUNTRY OR TRANSLATION **CLASS SUBCLASS** NUMBER PATENT OFFICE (YES/NO) DATE H.L H.M H.N H.O H.P H.Q OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) Bechtold et al., Injection Device, Pub. No. US 2002/O165500, 11/7/O2 H.R Polzin, Method for Reconstituting an Injection Liquid and an Injection Appliance for Carrying Out Such a Method, Pub. No. H.S US 2002/O173752, 11/21/O2 H.T Barker et al., Pre-Filled Safety Diluent Injector, Pub. No. US 2002/O177805, 11/28/O2 **DATE CONSIDERED EXAMINER** EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO. 10/817,224 PATENT AND TRADEMARK OFFICE PEDI/15A1 (MODIFIED) INFORMATION DISCLOSURE **APPLICANT** STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **GROUP FILING DATE** (Use several sheets if necessary) April 1, 2004 (37 CFR 1.98(b)) **U.S. PATENT DOCUMENTS** FILING DATE **ISSUE EXAMINER** IF APPROPRIATE **SUBCLASS** PATENT NUMBER DATE **PATENTEE CLASS** INITIAL 2 8 9 7/21/98 Chen et al. I.A 8 5 3 8/18/98 I.B 5 7 9 3 6 Romano et al. 10/20/98 5 8 2 3 9 9 Yamagata I.C 8 I.D 5 8 4 3 0 3 6 12/01/98 Olive et al. 12/22/98 5 9 Marano et al. I.E 8 5 1 8 0 0 1/12/99 I.F 8 5 8 Capaccio 3/9/99 9 5 8 7 3 3 8 Mahurkar I.G 7/6/99 9 9 6 5 I.H 5 Benson 7/6/99 1.1 5 9 9 6 Mulhauser et al. I.J 5 9 2 1 9 6 4 7/13/99 Martin 5 9 2 1 9 6 3 7/13/99 Erez et al. FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS TRANSLATION **DOCUMENT PUBLICATION COUNTRY OR** SUBCLASS PATENT OFFICE **CLASS** (YES/NO) NUMBER DATE I.L I.M I.N 1.0 I.P I.Q OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) I.R Barker et al., Pre-Filled Safety Vial Injector, Pub. No. US 2002/O177819, 11/28/O2 Cocker et al., Safety Device, Pub. No. 2002/O193748, 12/19/O2 I.S I.T Righi et al., Disposable Safety Syringe, Pub. No. US 2003/O004468, 1/2/O3 **EXAMINER** DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered. Include a copy of this form with next communication to applicant.

U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. SUBSTITUTE FORM PTO-1449 PATENT AND TRADEMARK OFFICE PEDI/15A1 10/817,224 (MODIFIED) INFORMATION DISCLOSURE **APPLICANT** STATEMENT BY APPLICANT Gilbert R. Gonzales et al. **GROUP** (Use several sheets if necessary) **FILING DATE** (37 CFR 1.98(b)) April 1, 2004 **U.S. PATENT DOCUMENTS** FILING DATE EXAMINER ISSUE IF APPROPRIATE PATENT NUMBER **CLASS SUBCLASS** DATE **PATENTEE** INITIAL 8 7/27/99 Marshall J.A 5 9 2 2 0 5 9/14/99 J.B 5 9 5 1 1 6 Bunyan 5 9 8 0 9 11/9/99 J.C 4 Hansen 5 9 4 9 0 11/16/99 J.D 8 0 Mikkelsen 11/16/99 5 9 8 4 8 9 D'Alessio et al. J.E 9 J.F 6 0 5 4 3 8 1/18/00 Shaw 0 5 3 1/18/00 J.G 6 9 6 Buttgen et al. 3/7/00 J.H 6 0 3 3 4 Losken et al. J.I 6 0 3 9 3 3/21/00 Botich et al. 6 0 4 8 3 3 6 4/11/00 Gabriel J.J J.K 6 0 5 6 7 2 8 5/2/00 von Schuckmann FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS DOCUMENT **PUBLICATION** COUNTRY OR TRANSLATION **CLASS SUBCLASS** PATENT OFFICE (YES/NO) NUMBER DATE J.L J.M J.N J.O J.P J.Q OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) Leung et al., Fast Dissolving Orally Consumable Films, Pub. No. US 2003/O008008, 1/9/O3 J.R Giambattista et al., Pen Needle and Safety Shield System, Pub. No. 2003/0014018, 1/16/03 J.S Heiniger et al., Injection Device and Needle Covering Device, Pub. No. US 2003/O040716, 2/27/O3 J.T DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered. Include a copy of this form with next communication to applicant.

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